

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

September 25, 2018
Commonwealth Conference Center
Second Floor
Board Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: The meeting of the Board of Pharmacy was called to order at 9:08 a.m.

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT: Cynthia Warriner (arrived 9:17 a.m.)
Glenn L. Bolyard, Jr.
Melvin L. Boone, Sr.
James L. Jenkins, Jr.
Ryan K. Logan (arrived 9:34 a.m.)
Cheryl H. Nelson
Kristopher S. Ratliff
Patricia Richards-Spruill
Rebecca Thornbury

STAFF PRESENT: Caroline D. Juran, Executive Director
James S. Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Allyson K. Tysinger, Sr. Assistant Attorney General
David E. Brown, Director, DHP
Elaine Yeatts, Senior Policy Analyst, DHP
Sheralee Copeland, Executive Assistant

QUORUM: A quorum was established.

APPROVAL OF AGENDA: The agenda was unanimously approved as presented. (motion by Jenkins, second by Boone)

APPROVAL OF MINUTES: A handout of the draft minutes for the September 4, 2018 Ad Hoc Committee meeting was provided and considered for approval, in addition to the following minutes:

- ❖ June 20, 2018, Inspection Special Conference Committee
- ❖ June 20, 2018, Ad Hoc Committee for Routine Pharmacy Inspection Process
- ❖ June 21, 2018, Public Hearing to Schedule Certain Chemicals in Schedule I and to confirm to DEA scheduling
- ❖ June 21, 2018, Full Board Meeting
- ❖ July 19, 2018, Special Conference Committee

- ❖ August 14, 2018, Formal Hearings
- ❖ August 15, 2018, Special Conference Committee
- ❖ August 23, 2018, Public hearing to received comment on proposed regulations replacing emergency regulations for issuance of CSR's to community organizations to distribute naloxone and for tele-prescribing

MOTION:

The Board voted unanimously to adopt the minutes from June 20, 2018 through September 4, 2018, as presented. (motion by Nelson, second by Thornbury)

PUBLIC COMMENTS:

The board restricted public comments to two minutes each. A timer was projected on the screens in the room.

Randall Eads, a city manager for Bristol, Virginia, offered comment in support of the Dharma Pharmaceuticals pharmaceutical processor application.

Jeff Roden offered comment on the fees and proposed the idea of waiving the fee for children and spouses.

Peter Moore – Name appeared on the sign-up sheet to offer comment, but did not show when name was called.

Jim Layton offered support for Dalitso, LLC and Virginia-based research oriented facilities.

Nicole Miller commented on behalf of caregivers and expressed concern for the existing costs associated with taking care of a disabled child or incapacitated adult. Recommended the registration fees be valid for two years, similar to the Board of Medicine licensure requirements for physicians.

Michael Johnson, RPh, who owns Michael's Pharmacy in Abingdon, Virginia, offered support for the Dharma Pharmaceuticals pharmaceutical processor application.

Regina Whitsett, executive director of SAFE drug coalition in Chesterfield County and member of Coalitions of Virginia, offered comment in opposition of the laws authorizing pharmaceutical processors to dispense cannabidiol oil and THC-A oil, and offered support for FDA-approved products such as Epidiolex.

Christine Barrille, executive director of VPHA, expressed

support for the board's efforts in overseeing pharmaceutical processors and requested the pharmacist-in-charge language remain intact.

Michelle Peace, a Virginia Commonwealth University professor, commended the Board on including language that labs should be independent from all other persons. She recommended labs be located in Virginia since the DEA places the oils into Schedule I.

DIRECTOR'S REPORT:

Dr. David Brown, Director of the Department of Health Professions, welcomed the new Board members to the Board of Pharmacy. Dr. Brown commented on the importance of this being a "working" board and it will consist of active involvement from all members. Dr. Brown thanked the Board for its hard work and the work that is forthcoming. Dr. Brown reminded the board members to always put on your board "hat" and remember that we are here to serve the citizens of Virginia.

REGULATORY ACTIONS:

Ms. Yeatts reviewed the Chart of Regulatory Actions included in the agenda packet. She stated the regulatory packet that includes a provision for a pharmacist to dispense a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration is scheduled to become effective October 31, 2018.

- ❖ Adoption of the Exempt Regulation to add certain chemicals to Schedule I

Ms. Yeatts reviewed the draft amendments to Regulation 18VAC110-20-322 to incorporate certain chemicals into Schedule I. The public hearing was conducted that morning prior to the full board meeting.

MOTION:

The board voted unanimously to adopt as final Regulation 18VAC110-20-322 by inserting subsection C which states:

"C. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid: N-[2-(dimethylamino)cyclohexyl]-N-methyl-1,3-benzodioxole-5-carboxamide (other names: 3,4-methylenedioxy U-47700 or 3,4-MDO-U-47700), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is

possible within the specific chemical designation.

2. Cannabimimetic agent: N-(adamantanyl)-1-(5-chloropentyl) indazole-3-carboxamide (other name: 5-chloro-AKB48), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until (18 months after the effective date of the regulation) unless enacted into law in the Drug Control Act.” (motion by Warriner, second by Thornbury)

- ❖ Adoption of Proposed Regulations for Pharmaceutical Processors of CBD Oil and THC-A Oils

Ms. Yeatts reviewed the Emergency Regulations and advised that the underlined text in the agenda packet starting on page 82 reflects the amendments adopted by the board in June 2018 and that the highlighted text reflects recommended changes based on recent public comment.

Ms. Yeatts reviewed the Timeline for Promulgation of Emergency Regulations found on page 48 of the agenda packet. Once approved the OAG, DPB, SHHR, and Governor, the proposed regulations adopted on 9/25/18 will be open for a 60-day comment period and public hearing. Emergency regulations expire on 2/9/19 and the board will have to request a 6-month extension since it will not be possible for the permanent regulations to be in effect by that date.

In addition to staff’s suggested amendments provided in the agenda packet based on public comment, the Board recommended additional amendments.

Following the review of 18VAC110-60-20, Mr. Ratliff expressed concern for the proposed fee for replacement of a patient/parent/guardian’s registration whose information has changed such as with a change of address. It was recommended that this fee be stricken.

MOTION:

The Board unanimously voted to amend the language in 18VAC110-60-20 (C5) to read as follows: “Replacement of registration for a qualifying patient or parent or legal guardian whose original registration certificate has been lost, stolen, or destroyed.” and to strike “shall submit the fee for a replacement registration” from 18VAC110-

60-70(C). (motion by Ratliff, second by Warriner).

In reviewing page 103, 18VAC110-60-170(D), Ms. Richards-Spruill recommended the provision for a pharmacy intern should be limited to after completing their first professional year of schooling.

MOTION:

The Board voted unanimously to amend 18VAC110-60-170(D) by inserting “who has completed the first professional year,” after “...a registered pharmacy intern”. (motion by Richards-Spruill, second by Warriner)

After Ms. Yeatts reviewed 18VAC110-60-200(A), page 107, Ms. Thornbury questioned if the regulation should also prohibit the PIC of a pharmaceutical processor from being the PIC of a pharmacy.

MOTION:

The Board voted unanimously to amend 18VAC110-60-200(A) by inserting “or of a pharmacy” prior to “at any time.” (motion by Thornbury, second Nelson)

Upon reviewing 18VAC110-60-210 (H), on page 110, Ms. Richards-Spruill recommended inserting language to require counseling on proper disposal.

MOTION:

The Board voted unanimously to amend the language in 18VAC110-60-210(H) by inserting at the end of the second sentence “and disposal of the oils in a manner that renders them non-recoverable.” (motion by Warriner, second by Richards-Spruill)

After reviewing 18VAC110-60-240 (D) on page 117, Mr. Boone recommended changing the requirement for testing security equipment from “no less than two times per year” to “at least every 6 months”.

MOTION:

The Board voted unanimously to amend 18VAC110-60-240(D) to read as follows: “The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested at least every 6 months.” (motion by Boone, second by Warriner)

Upon reviewing the Test Specification table 1 under

18VAC110-60-300 on page 128, Ms. Nelson noted the needed change from uppercase units to lowercase units, i.e., “uG/KG” to “ug/kg” and recommended “BW” be spelled out to read “By weight”. No motion needed for this technical amendment.

Upon reviewing 18VAC110-60-330 (A) on page 133, Ms. Nelson expressed concern with regards to ensuring patient’s ability to have an easy method of disposal. Mr. Logan commented that the patient needs a method to return the product to the pharmaceutical processor for destruction, if necessary. Mr. Ratliff commented that once a traditional drug has been dispensed, it cannot be returned to the pharmacy. Ms. Juran advised that staff will research the topic and the board can consider the matter at a future meeting.

Staff noted that the word “pharmacy” in 18VAC110-60-330(B) should be changed to “pharmaceutical processor”. No motion needed for this technical amendment.

MOTION:

The Board voted unanimously to adopt the proposed regulations as presented and amended for Pharmaceutical Processors of CBD Oil and THC-A Oil. (motion by Thornbury, second by Bolyard)

Adoption of Final Regulations for Issuance of Controlled Substances Registration (CSR)

Ms. Yeatts announced that the Board needs a motion to adopt the Final Proposed Regulations.

MOTION:

The Board voted unanimously to adopt the Final Regulations – Issuance of Controlled Substances Registration (CSR). (motion by Warriner, second by Boone)

Extension of Emergency Regulations for Issuance of Controlled Substances Registration

Ms. Yeatts announced the staff note on page 145 of the agenda packet regarding the extension of the CSR Regulations.

The emergency regulations for issuance of a CSR to: 1) persons who have been trained in the administration of naloxone in order to possess and dispense the drug to persons receiving training; and 2) an entity for the purpose of establishing a bona fide practitioner-patient for prescribing when treatment is provided by telemedicine in accordance with federal rules expire on November 7, 2018. The Boards can adopt final regulations fifteen days after the

close of the comment period on proposed regulations (comment closes on September 7, 2018), but final regulations cannot be in effect by expiration of the emergency regulations.

MOTION:

The Board voted unanimously to approve the request to extend the Emergency Regulations for Issuance of a Controlled Substance Registration (CSR) for six months beyond the expiration of November 7, 2018. (motion by Warriner, second by Boone)

Consideration of Regulatory Action for
White Bagging and Brown Bagging

Ms. Yeatts announced that there is a copy of the NOIRA background document and also a copy of the comments received on the NOIRA included in the agenda packet. Ms. Yeatts reviewed the Staff Note included on page 146 of the agenda which reads: The comment period on the NOIRA has closed. It is recommended that the Regulation Committee consider the comment, regulation in other states, and other related information and draft proposed regulations for the Board's consideration.

MOTION:

The Board voted unanimously to refer the issue of white bagging and brown bagging to the Regulation Committee for it to consider comment received, discuss regulations in effect in other states and other related information, and to draft proposed regulations for the Board's consideration. (motion by Jenkins, second by Nelson)

Summary of 2019 Legislative Proposals
Submitted by DHP

Ms. Yeatts reviewed the Summary of Legislative Proposals Submitted by DHP on page 171 of the agenda packet which included:

- ❖ E-prescribing implementation (Bill attached to agenda packet);
- ❖ Process for placement of drugs under seal or seizure by Board or law enforcement (Bill attached to agenda packet);
- ❖ Correction of circular mandatory suspensions and inconsistency in the Code;
- ❖ Flexibility in terms of board members to re-balance expiration dates and fill certain vacancies; and,
- ❖ Practice by dental hygienists under remote supervision; authority to administer certain topical drugs.

Closed Meeting:

Upon a motion by Ms. Warriner , and duly seconded by Mr. Boone, the Board unanimously voted at 11:03 a.m. to

convene a closed session pursuant to Virginia Code Section §2.2-3711(A)(8) to receive legal advice regarding the Virginia Freedom of Information Act and the consideration of the applications for pharmaceutical processor permits. In addition, the Board moved that Caroline Juran, Jim Rutkowski, Allyson Tysinger, Elaine Yeatts, Sammy Johnson, Sheralee Copeland, Scott Maye, and Scott Parsons attend the closed session because their presence was necessary and would reasonably aid the board.

Reconvene:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed, or considered during the closed session just concluded. (motion by Warriner, second by Boone)

Board Member Statements:

Mr. Ratliff announced that he had written a letter of support for one of the pharmaceutical processor applicants prior to being appointed to the Board and that he would recuse himself from the Board's consideration of the pharmaceutical processor applications. Mr. Ratliff exited the room.

Mr. Saenz announced that as part of his responsibilities serving as the Pharmacy Director of the UVA Hospital Pharmacy, he also serves as an assistant dean of VCU School of Pharmacy at a satellite campus located in Charlottesville. He stated that he believes he can render a fair and impartial decision in the consideration of pharmaceutical processor applications.

Closed Meeting:

Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the board unanimously voted at 12:00 p.m. to convene in closed session pursuant to Virginia Code sections § 54.1-108 and § 2.2-3711(A)(5) to evaluate the applications for pharmaceutical processor permits to determine which, if any, should be awarded conditional approval. In addition, the Board moved that Caroline Juran, Jim Rutkowski, Allyson Tysinger, Elaine Yeatts, Sammy Johnson, Sheralee Copeland, Scott Maye, and Scott Parsons attend the closed session because their presence was necessary and would reasonably aid the Board.

Reconvene:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed, or considered during the closed session just concluded. (motion by Warriner, second by Boone)

MOTION:

Upon a motion by Mr. Logan, and duly seconded by Ms. Richards-Spruill, the Board conditionally approved the applications for a pharmaceutical processor permit of Pharmacann in health service area I, Dalitso in health service area II, Green Leaf in health service area IV, and Columbia Care in health service area V for the reasons that will be stated in the Board's forthcoming orders. In addition, the Board moved that the conditional approval of these applications is conditioned on the satisfactory result of criminal background checks on the owners of each applicant as further detailed in the Board's forthcoming orders. The Board further moved to deny all other applications for a pharmaceutical processor permit in these regions because under Virginia Code § 54.1-3442.6, the Board may only issue one permit for each health service area and for other reasons that will be stated in the Board's forthcoming orders. Finally, under Virginia Code § 2.2-4021, the Board moved that Board staff prepare and issue orders consistent with the Board's decisions within 90 days of today's date.

MOTION:

Upon a motion by Mr. Boone, and duly seconded by Mr. Bolyard, the Board conditionally approved the application for a pharmaceutical processor permit of Dharma in health service area 3 for the reasons that will be stated in the Board's forthcoming order. In addition, the Board moved that the Board's approval of this application be conditioned on the satisfactory result of criminal background checks on the owners of the applicant as further detailed in the Board's forthcoming order. The Board further moved that the Board deny all other applications for a pharmaceutical processor permit in this region because under Virginia Code § 54.1-3442.6, the Board can only issue one permit for each health service area and for other reasons that will be stated in the Board's forthcoming orders. Finally, under Virginia Code § 2.2-4021, the Board moved that

staff prepare and issue orders consistent with the Board's discussion within 90 days of today's date.

MOTION:

Upon a motion by Mr. Jenkins, and duly seconded by Ms. Nelson, the Board moved that for the purposes of conducting criminal background checks pursuant to Virginia 18VAC110-60-110 (B)(3), checks be performed for owners with an interest of 5% or more of each conditionally approved applicant.

Chairman's Report:

Mr. Saenz thanked everyone for their hard work in reviewing and considering the pharmaceutical processor applications.

Report on Board of Health Professions:

Mr. Logan did not have anything to report.

Report on Licensure Program:

Mr. Johnson reported the Board currently licenses 37,812 individuals and facilities. The Board issued 1,308 licenses and registrations for the period of June 1, 2018 through August 31, 2018. Inspectors conducted 525 facility inspections including 242 routine inspections of pharmacies: 93 (38%) resulted in no deficiency, 75 (31%) with deficiencies and 74 (31%) with deficiencies and a consent order. There were 9 instances where "First Documented Occurrence" was noted for a deficiency that would have resulted in a monetary penalty. Pharmacies with a "First Documented Occurrence" will incur a monetary penalty if the same deficiency is noted on the next routine inspection.

Report on Disciplinary Program:

Ms. Shinaberry commended and recognized the hard work of Rose DeMatteo and Ileita Redd during the absence of Kennia Butler, Discipline Program Specialist. She also commented on the utilization of overtime assistance from Donna Lee with the Board of Dentistry.

Ms. Shinaberry reported that there are 43 patient care cases at PC as compared to 16 that were reported in June. However, 14 of these cases have been offered a CCA or PHCO, and 17 of these cases are pending an IFC or FH. There are 5 patient care cases that exceed 250 work days

(this is substantially below our 10% threshold for open cases). Non-patient care cases are inspection cases or compliance related cases. We are beginning to see a slight decrease in the number of inspection cases resulting in a PHCO. Possible summary suspension cases have tapered down to a more normal volume. Ms. Shinaberry briefly reviewed the upcoming disciplinary proceedings.

Executive Director's Report:

Ms. Juran reported on the status of the Paperless License Initiative. The goal is to print a one-time license without an expiration date and refer individuals to the online License Lookup feature for information regarding licensure status. She stated this initiative will not be in place prior to the December 31 renewal deadline for pharmacists and pharmacy technicians, but will hopefully be implemented in spring 2019. Ms. Juran announced that a Board e-newsletter was published September 2018. Ms. Juran also discussed the Hurricane Waiver Provisions that were in place for patients displaced to Virginia to get their medications during Hurricane Florence. She also reported on recent presentations and meetings.

ADJOURN:

With all business concluded, the meeting adjourned at approximately 5:38 p.m.

Rafael Saenz, Chairman

Caroline Juran, Executive Director

DATE:

DATE: